(frovatriptan succinate). FROVA is indicated for the acute treatment of migraine attacks with or without aura in adults. Subsequent to this approval, the Patent and Trademark Office received two patent term restoration applications for FROVA (U.S. Patent Nos. 5,464,864 and 5,616,603) from Vernalis, Ltd., and the Patent and Trademark Office requested FDA's assistance in determining these patents' eligibility for patent term restoration. In a letter dated July 16, 2003, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of FROVA represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for FROVA is 2,201 days. Of this time, 1,186 days occurred during the testing phase of the regulatory review period, while 1,015 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(i)) became effective*: November 1, 1995. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on November 1, 1995.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act*: January 29, 1999. FDA has verified the applicant's claim that the new drug application (NDA) for FROVA (NDA 21–006) was initially submitted on January 29, 1999.

3. *The date the application was approved*: November 8, 2001. FDA has verified the applicant's claim that NDA 21–006 was approved on November 8, 2001.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 1,096 days of patent term extension for patent 5,464,864 and 586 days of patent term extension for patent 5,616,603.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and ask for a redetermination by March 29, 2004. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by July 27, 2004. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Division of Dockets Management. Three copies of any mailed information are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 13, 2004.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. 04–1840 Filed 1–28–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003E–0245]

Determination of Regulatory Review Period for Purposes of Patent Extension; REMODULIN

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for REMODULIN and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent that claims that human drug product.

ADDRESSES: Submit written comments and petitions to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.*

FOR FURTHER INFORMATION CONTACT: Claudia Grillo, Office of Regulatory Policy (HFD–013), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 240–453–6699.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted, as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product REMODULIN (treprostinil sodium). REMODULIN is indicated as a continuous subcutaneous infusion for the treatment of arterial pulmonary hypertension in patients with NYHA class II–IV symptoms to diminish symptoms associated with exercise. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for REMODULIN (U.S. Patent No. 5,153,222) from United Therapeutics, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated July 16, 2003, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of REMODULIN represented the first permitted commercial marketing or use of the

product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for REMODULIN is 4,026 days. Of this time, 3,443 days occurred during the testing phase of the regulatory review period, while 583 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(i)) became effective*: May 15, 1991. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on May 15, 1991.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act*: October 16, 2000. FDA has verified the applicant's claim that the new drug application (NDA) for REMODULIN (NDA 21–272) was initially submitted on October 16, 2000.

3. The date the application was approved: May 21, 2002. FDA has verified the applicant's claim that NDA 21–272 was approved on May 21, 2002.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 337 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and ask for a redetermination by March 29, 2004. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by July 27, 2004. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Division of Dockets Management. Three copies of any mailed information are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 13, 2004.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. 04–1841 Filed 1–28–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Record of Decision—Construction and Operation of an Integrated Research Facility by the National Institutes of Health at Fort Detrick, MD

AGENCY: Department of Health and Human Services, National Institutes of Health (NIH) United States Army Garrison (USAG), Fort Detrick.

ACTION: Notice. The Department of Health and Human Services, NIH, and the United States Army Garrison, Fort Detrick (Cooperating Agency), have decided, after completion of a Final Environmental Impact Statement (EIS) and a thorough consideration of public comments on the Draft EIS, to implement Alternative I (Proposed Action), which was identified as the Preferred Alternative in the Final EIS. This action involves the construction and operation of an Integrated Research Facility (IRF) by NIH on a site adjacent to existing U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) facilities at Fort Detrick, Maryland.

The National Institute of Allergy and Infectious Diseases (NIAID), a component of NIH, will be the occupant of the facility, which will contain Intramural NIAID bio-safety level –2, –3, and –4 laboratory and animal research facilities for conducting biodefense and emerging infectious disease research. NIAID's biodefense mission is different but complementary to USAMRIID's. The selected action best satisfies NIH's needs and the biodefense research goals of NIAID and USAMRIID. Moreover, it fosters increased interagency collaboration between NIH and U.S. Army scientists by building on the already well established formal cooperation that exists between these two organizations. NIH will incorporate design and operational safeguards in the facility to protect laboratory workers and local residents from possible harmful effects related to the operation of the facility, however remote these occurrences may be. This action also allows NIH to address a critical national shortage in bio-safety level-4 (BSL–4) capability.

FOR FURTHER INFORMATION CONTACT: Mr. Ronald Wilson, Master Planner, Division of Facilities Planning, ORF, National Institutes of Health, 31 Center Drive, Room 3B44, MSC 2162, Bethesda, Maryland, 20817–2162, telephone 301–496–5037, e-mail: *wilsoron@ors.od.nih.gov.*

SUPPLEMENTARY INFORMATION: The National Institutes of Health (NIH) and United States Army Garrison, Fort Detrick (USAG), have prepared this Record of Decision (ROD) on a Final EIS for the construction and operation of an Integrated Research Facility by NIH at Fort Detrick, Maryland. This ROD includes:

1. The final decision;
2. All alternatives considered, specifying the alternative or alternatives which were considered to be environmentally preferable;
3. A discussion of factors which were involved in the decision, including any essential considerations of national policy which were balanced in making the decision and a statement of how those considerations, if any, entered into the decision;
4. A statement of whether all practicable means to avoid or minimize potential environmental harm from the selected alternative have been adopted, and if not, why they were not;
5. A description of mitigation measures that will be undertaken to make the selected alternative environmentally acceptable;
6. A discussion of the extent to which pollution prevention is included in the decision and how pollution prevention measures will be implemented; and
7. A summary of any monitoring and enforcement program adopted for any mitigation measures.

Alternatives Considered

Two reasonable alternatives were identified and considered in the Final EIS. They are (1) Alternative I, the Proposed Action, and, (2) the No Action Alternative. The Proposed Action is described above. Under the No Action Alternative, NIH would not build the IRF thereby eliminating the negligible to minor adverse impacts associated with implementation of the selected action. Selection of the No Action alternative, however, would prevent NIH and the public from realizing the health and safety benefits that would derive from the research conducted in the planned IRF. This research will focus on disease-causing organisms that might emerge naturally or be used as agents of